

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing

BOARD OF CHIROPRACTIC EXAMINERS

MINUTES OF THE TELEPHONIC MEETING

Thursday, October 8th, 2015

These are DRAFT minutes prepared by the staff of the Division of Corporations, Business and Professional Licensing. These minutes have not been reviewed or approved by the Board.

By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62, Article 6, a scheduled teleconference of the Board of Chiropractic Examiners was held at the State Office Building, 333 Willoughby Avenue, Thursday, October 8th, 2015, beginning at 2:01 p.m. The meeting was held in Conference Room B, 9th Floor, Juneau, Alaska.

Agenda Item 1 Call to Order/Roll Call

The meeting was called to order by Chair, James Heston at 2:01 p.m.

Board Members Present, constituting a quorum:

James Heston, Doctor of Chiropractic (telephonically)
Daniel Holt, Doctor of Chiropractic (telephonically)
Walter Campbell, Doctor of Chiropractic (telephonically)
Edward Barrington, Doctor of Chiropractic (telephonically)
Christine Hill, Public Member (telephonically)

Attending from the Division of Corporations, Business and Professional Licensing were:

Laura Carrillo, Licensing Examiner
Dawn Hannasch, Records & Licensing Supervisor
Sara Chambers, Operations Manager
Charles Ward, Paralegal
Harriet Dinegar, Attorney (telephonically)
Angela Birt, Chief Investigator (telephonically)
Brian Howes, Investigator (telephonically)

Attending (telephonically) from Myoscience were:

Tracey Henry, Vice President of Regulatory, Quality and Clinical
Johanna Beckman, Vice President of Sales and Marketing
Jessica Preciado, Principal Scientist and Director of Product Development

Attending from the profession or public:

Billy McAfee, Chiropractor (telephonically)
Amy Welch, Associate Attorney (telephonically)

Agenda Item 2 Review Agenda

Time: 2:01 p.m.

Dr. Heston informed the Board that he would like to amend the agenda as Myoscience staff were already in attendance.

Agenda Item 5 Iovera

Time: 2:02 p.m.

Dr. Heston inquired to Myoscience whether Iovera^o is considered a surgical procedure, to which Tracey Henry responded that it is. Dr. Jessica Preciado also clarified that Iovera is considered a minimally invasive surgical procedure. Dr. Heston then asked whether injectable anesthetics were required, or if Iovera^o could be administered with the use of a topical cold spray. Dr. Preciado responded that although use of anesthetics doesn't affect the efficacy of the treatment, it is part of the training and is used for patient comfort. Dr. Preciado added that to her knowledge, cold spray has not been used as an analgesic, but that injectable anesthetics are typically used. Tracey Henry similarly responded that she was unaware of cold spray for anesthetic use.

Myoscience was then again inquired about whether Iovera^o is a surgical procedure, to which Dr. Preciado again clarified. Christine Hill commented that Myoscience had confirmed this earlier, after which time she asked if there was more information regarding cold spray. Dr. Preciado stated that as mentioned on the product label, some form of injectable anesthetic is used. Dr. Preciado further added that no purchaser of the device has been trained to use cold spray to date. Tracey Henry commented that use of anesthetics is ultimately up to the physician, and that to her knowledge, only one physician administers the device occasionally without the use of anesthetics when using the shorter needle tip. Ms. Henry added that to do so would be uncomfortable and difficult for the patient.

Dr. Heston then prompted Myoscience to clarify if they only sell Iovera^o to *physicians*, and if they would consider a *Chiropractic* physician as a physician. Dr. Preciado and Tracey Henry

stated that the device is only sold to physicians, and that chiropractors are not considered physicians according to the FDA definition of “physician”. Tracey Henry informed the board that they are legally only allowed to sell to physicians. Dr. Holt similarly inquired whether Iovera has been sold to chiropractic clinics in other states, to which Dr. Preciado reiterated that Iovera is only sold across the states to physicians and some specialty clinics, including those staffed by orthopedic surgeons.

Myosience left the room telephonically at 2:08 p.m.

Agenda Item 3 Ethics

Time: 2:09 p.m.

Dr. Heston addressed ethics per the Executive Branch Ethics Act, AS 39.52, namely that Dr. Campbell was not to participate in discussion or to vote for or against Iovera°. Dr. Heston prompted Dr. Holt to make a statement regarding his participation at this teleconference meeting. Dr. Holt stated that since the previous meeting and after careful review, he had collected his thoughts and was ready to participate in discussion and voting at this meeting.

Agenda Item 4 Reinstatement

Time: 2:13 p.m.

Dr. Heston then informed the Board that he would like to go into executive session. Harriet Milks reminded the Board to be clear on record as to the reason for going to executive session. Dr. Heston commented that it was for the purpose of discussing reinstatement of a licensee under AS 44.62.310(c)(4).

On a motion duly made by, seconded by, Christine Hill, seconded by Daniel Holt and approved unanimously, it was:

RESOLVED to enter into executive session for the purpose of discussing reinstatement of a licensee under AS 44.62.310(c)(4).

No vote or decision was made during the executive session.

Off Record at 2:15 p.m.

On Record at 2:26 p.m.

Following executive session, Dr. Heston addressed Dr. Campbell as he was not previously connected to the teleconference at the time of initial discussion during Agenda Item #3. As the designated ethics supervisor, Dr. Heston reiterated to Dr. Campbell that since he recused himself from voting during the last meeting, he was not to participate in discussion or vote for or against Iovera°. Dr. Campbell agreed.

The Board returned to discussion on Iovera^o and informed the Board that after careful review of the audio from the previous meeting, he and the Division concluded that only a motion was made, not a vote. Dr. Campbell commented that after discussion with Myoscience, it appears as though the Board was only given partial information from the individuals who desired to administer this device. Dr. Barrington also reiterated that Myoscience doesn't acknowledge use of cold spray, and as such, the information persuaded him to change his vote from yes to no. Christine Hill agreed. Dr. McAfee then attempted to provide a response, to which Dr. Heston asserted he could not participate in the discussion.

Dr. Holt then reiterated the information previously provided by Myoscience that injectable anesthetics are used. Dr. Barrington then commented that this may be a matter better discussed best between Myoscience and the individuals who desired to use Iovera.

On a motion to approve use of Iovera within the scope of chiropractic made by Daniel Holt, seconded by, Christine Hill, and approved unanimously, it was:

RESOLVED to deny the use of Iovera^o within the scope of chiropractic.

Attorney, Harriet Milks commented that the Board's vote against Iovera^o may lead to a change in regulation to more clearly define surgery. Harriet Milks inquired whether the Board wanted to make any other vote in relation to the discussion of the device and its procedural practices as previously described by Myoscience. Christine Hill commented that legislators should take this matter upon themselves. Harriet Milks referenced the time when the Board was in discussion regarding injectable nutrients, and that the result of such discussion led to sending notices to the licensees. Ms. Milks suggested that the Board may want to delegate to the licensing examiner the task of drafting letters of the Board's determination on Iovera^o. Ms. Milks clarified that the Board could make a draft specifically stating what the letter would include, for which Ms. Carrillo could finalize and send it out. Dr. Heston commented that the letter would include something to the effect of Iovera^o being considered a surgical procedure that requires injectable anesthetics.

Dr. Barrington commented on his sentiment that the chiropractic profession would benefit from expanding to include advances in technology, to which the Board collectively agreed. Dr. Holt added that although advancement of the chiropractic profession is ideal, the procedure surrounding Iovera^o is currently not within the chiropractic scope. The Board discussed sending notices. Since the Board was ahead of schedule, Christine suggested allowing public comment to proceed immediately, followed by a revisit to public comment at the scheduled 3:30 p.m. time period.

Task:

The Board will work with examiner, Laura Carrillo to draft a letter in regards to Iovera^o

Agenda Item 6 Public Comment**Time: 2:42 p.m.**

Amy Welch, Associate Attorney for Drs. McAfee and Shannon addressed the Board's comment that they were misled by the two chiropractors at its previous meeting on September 18th, asserting that Drs. McAfee and Shannon were only acting based upon the information that was initially provided to them by Myoscience. Ms. Welch added that in fact, the information provided by Myoscience during this teleconference was in contrast to the information provided in earlier correspondence between the said company and Drs. McAfee and Shannon (chiropractors)—specifically that they were offered the device without the use of lidocaine. Amy Welch then commented that Myoscience was just simply throwing around the word “surgery”, adding that there are several definitions of surgery. Ms. Welch then inquired to the Board to clarify whether they were using the Chiropractic statutes/regulations' definition of surgery, or the definition of surgery as used by Myoscience. Ms. Welch asserted that the Board should be relying on its own definition of surgery under 12 AAC 16.990(5)(6), and that Iovera^o is not considered a surgical procedure within the stated regulation. Ms. Welch then addressed Myoscience's earlier comment that there is one *physician* who doesn't use anesthetics, therefore it is interpreted that administering Iovera^o doesn't specifically require an anesthetic.

Dr. McAfee then stated that the Board's comment about Drs. McAfee and Shannon being misleading is insulting. In invalidating the Board's assumption, Dr. McAfee referenced his direct communication with Myoscience, who had previously offered the device without the use of lidocaine. Dr. McAfee also stated that Myoscience previously informed him that there were multiple physicians across the country who were not administering Iovera^o with any analgesic. Dr. McAfee then commented on Iovera^o's placement into the many conflicting definitions of surgery, asserting that the device would be accepted within the general Alaska statutory definition.

Dr. Barrington commented that negative perception of Drs. McAfee and Shannon were unintentional, but that the matter appears to be best discussed between the chiropractors and Myoscience. Dr. McAfee responded that the Board was unable to make an informed decision because they lacked pertinent information regarding Iovera^o that otherwise could have been obtained had the Board allowed Dr. McAfee to provide clarification. Dr. McAfee specifically noted that Dr. Heston did not allow him to do so. Christine Hill expressed her regret in the decision made by the Board, but asserted that she felt comfortable with her informed decision. Dr. McAfee maintained that the Board did not make an informed

decision and that due process was not provided. Dr. McAfee concluded that the Board would be hearing from him again regarding this issue.

Billy McAfee, Amy Welch, and Harriet Dinegar left the room at 2:51 p.m.

Off record at 2:51 p.m.

On record at 3:30 p.m.

Agenda Item 6 Public Comment

Time: 3:30 p.m.

No one was present for additional public comment.

Agenda Item 8 Adjourn

Time: 3:32 p.m.

On a motion duly made by Daniel Holt, seconded by Christine Hill, and approved unanimously, it was:

RESOLVED to adjourn the meeting.

Respectfully Submitted by:

Laura Carrillo
Licensing Examiners

Approved by:

Dr. James Heston, Chair
Alaska State Board of Chiropractic Examiners